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SEP 2 0 2005

SPECIAL 510(k) SUMMARY for the line extension of
INION CPS ™ Baby 1.5 Bioabsorbable Fixation System (K010351)

MANUFACTURER

Inion Ltd., Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person

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DEVICE NAME

Trade name: Large X plate
Common/Usual Name: Bone plate

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification Panel: Dental
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone plate
Regulatory Class: Class II
Product Code: JEY

PREDICATE DEVICE

Howmedica Leibinger Resorbable Fixation System (K982531)

CONFORMANCE WITH PERFORMANCE STANDARDS

No applicable mandatory performance standards exist for this device.
Compliance to voluntary consensus standards is listed in the application.

THE REASON FOR SCPECIAL 510(k)

Additional plate design to Inion CPS™ Baby 1.5 Bioabsorbable Fixation System (K010351).

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion CPS™ Baby 1.5 Bioabsorbable Fixation System is indicated for use in trauma and reconstructive procedures in the craniofacial skeleton, mid-face and maxilla. Specific indications:

- Fractures of the cranium, mid-face and maxilla
- Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations)
- LeFort (I, II, III) osteotomies
- Pediatric reconstructive procedures
- Orthognathic or reconstructive procedures of the cranium, mid-face, or maxilla
- Craniotomy flap fixation.

The new large X plate is identical with the other implants in the previously 510(k) cleared Inion CPS™ Baby 1.5 Bioabsorbable Fixation System (K010351) in terms of copolymer composition, intended use and indications for use as described in the device labelling, manufacturing method, sterilization method and packaging solution.

Similar design from other manufacturers is currently commercially available and in clinical use.

EQUIVALENCE TO MARKETED PRODUCTS

Based on the performance data and specifications presented, it can be concluded that the intended use, material composition and scientific technology, degradation profile and mechanical properties of Inion CPS™ Baby 1.5 Bioabsorbable Fixation system large X plate are substantially equivalent with the other Inion CPS™ Baby 1.5 Bioabsorbable Fixation system (K010351) implants as well as the predicate device Howmedica Leibinger Resorbable Fixation System (K982531).

Inion CPS™ Baby 1.5 Bioabsorbable Fixation system large X plate is substantially equivalent to predicate Class II devices used in maintaining accurate alignment of bone fractures and osteotomies in the cranium and mid-face because the differences between Inion CPS™ Baby 1.5 Bioabsorbable Fixation system large X plate and the predicate devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2005

Ms. Hanna Marttila
Regulatory Affairs Director
Inion Limited
Laakarinkatu 2
Tampere,
FINLAND 33520

Re: K052444
Trade/Device Name: Inion CPS™ Baby 1.5 Bioabsorbable Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 25, 2005
Received: September 6, 2005

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device. subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052444

Indications for Use

510(k) Number (if known): _____

Device Name: Inion CPS™ Baby 1.5 Bioabsorbable Fixation System

Indications for Use:

A. General indications: The **INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM** is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, mid-face and maxilla.

B. Specific indications:
- Fractures of the cranium, mid-face and maxilla
- Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations)
- LeFort (I, II, III) osteotomies
- Pediatric reconstructive procedures
- Orthognathic or reconstructive procedures of the cranium, mid-face, or maxilla
- Craniotomy flap fixation

Contraindications:

The **INION CPS™ BABY 1.5 BIOABSORBABLE FIXATION SYSTEM** is not intended for use in and is contraindicated for mandibular tumor resection; active or potential infection; patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse). DO NOT use in the mandible.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K052444